



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/733,436	12/08/2000	Mark Fitchmun	PS-001MF.P	2693

26990 7590 01/30/2003

DAVID B. WALLER & ASSOCIATES
5677 OBERLIN DRIVE
SUITE 214
SAN DIEGO, CA 92121

EXAMINER

LEUNG, JENNIFER A

ART UNIT PAPER NUMBER

1764

DATE MAILED: 01/30/2003

5

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/733,436

Applicant(s)

FITCHMUN, MARK

Examiner

Jennifer A. Leung

Art Unit

1764

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-19 and 21 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-21 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Art Unit: 1764

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-19 and 21, drawn to a device and composition, classified in class 422, subclass 211.
 - II. Claim 20, drawn to a method of reducing the volatility of radioactive waste, classified in class 588, subclass 1+.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as apparatus and process for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the apparatus as claimed can be used to practice another and materially different process, such as the storage of non-radioactive toxic waste.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, recognized divergent subject matter, and search required for Group I not required for Group II, restriction for examination purposes as indicated is proper.

2. During a telephone conversation with Mr. David Waller on April 5, 2002, a provisional election was made without traverse to prosecute the invention of Group I, claims 1-19 and 21. Affirmation of this election must be made by applicant in replying to this Office action.

Art Unit: 1764

3. Claim 20 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Specification

4. The abstract of the disclosure is objected to because of the use of legal phraseology. Refer to the use of "comprising" (lines 2, 4), "said" (lines 3, 5) and "means" (line 3). Correction is required. See MPEP § 608.01(b).

Claim Objections

5. Claims 1 and 19 are objected to because of the following informalities. Appropriate correction is required. In claim 1, "a absorbent" (line 4) should be changed to -- an absorbent --. In claim 19, "a compositions" (lines 2-3) should be changed to -- a composition --.

Claim Rejections - 35 USC § 112

6. Claims 1-13, 17, 19 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 1, the phrase "insertable" (line 5) is considered vague and indefinite, since whether or not an element is capable of being inserted does not constitute a positive structural limitation. Furthermore, it is unclear as to the relationship between "a lid" (line 7) and "a lid" set forth in line 3, as well as the structural relationship of "a lid" to the other elements of the apparatus.

Regarding claims 2 and 3, the language of the claim is directed to a method limitation which renders the claim vague and indefinite as it is unclear as to what structural elements the

Art Unit: 1764

applicant is attempting to recite, since "said radioactive waste" is not considered an element of the apparatus as it is merely recited in the intended use clause of claim 1, line 1. Furthermore, in claim 2, it is unclear as to where "... a radioactive isotope selected from the group consisting of ^{125}I and ^{131}I ." is disclosed in the specification. Furthermore, in claim 3, it is unclear as to where "... a radioactive isotope selected from the group consisting of ^{36}Cl , ^{33}P , ^{32}P , ^{35}S , ^{18}F , ^{15}O , ^{14}C , ^{13}N , ^{11}C , and ^3H ." is disclosed in the specification.

Regarding claim 7, "said natural material" lacks proper positive antecedent basis.

Regarding claim 8, "said synthetic material" lacks proper positive antecedent basis.

Regarding claim 10, it is unclear as to whether the applicant is attempting to recite "dibasic/tribasic phosphonate salts" (line 3; spec. p. 6 line 29) or "dibasic/tribasic phosphate salts" (spec. p. 2 line 28). See also, "dibasic phosphonate salts" in claims 11 and 17.

Furthermore, it is unclear as to what is intended by "tribasic phosphonate salts" (line 3), for such a chemical compound does not exist since a phosphonate salt may be at most dibasic.

Regarding claim 19, it is unclear as to whether the applicant is attempting to recite "disodium phosphonate salts" (line 3; spec. p. 6 line 31) or "disodium phosphate salts" (spec. p. 2 lines 30-31; p. 3 line 10; p. 8 line 15). Furthermore, it is unclear as to the unit of measurement the applicant is attempting to recite by "parts" (i.e. parts by volume, parts by weight).

Regarding claim 21, it is unclear as to the relationship of "a receptacle" (line 3) to the "at least one receptacle" set forth in line 2. Furthermore, the phrase "may be" is considered vague and indefinite, since whether an element may be inserted does not constitute a positive structural limitation. Furthermore, it is unclear as to the relationship between the "at least one lid" (line 7)

Art Unit: 1764

and the "a lid" set forth in line 3, as well as the structural relationship of "at least one lid" to the other elements of the apparatus.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 14, 16-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Levy et al. (U.S. 4,081,402).

Regarding claim 14, Levy et al. disclose a composition comprising an absorbent matrix (i.e. hydrophilic polymer or hydrogel matrix; column 4, line 37-column 6, line 46), a humectant (i.e. ethylene glycol, glycerol; column 4, lines 59-65), a pH-stabilizing agent (i.e. phosphate buffer of pH 7.6; column 13, lines 38-40; column 14, lines 18-24) and an absorbent material (i.e. activated carbon, ion exchange resins; column 7, lines 31-55).

Regarding claim 16, Levy et al. further disclose the humectant may comprise glycerol (column 4, lines 61-65).

Regarding claim 17, Levy et al. further disclose the pH-stabilizing agent may be composed of a dibasic phosphate salt (i.e. dibasic potassium phosphate; column 14, lines 18-24). Please note that although the claim recites specifically "dibasic phosphonate salts", it is interpreted by the Examiner that the use of the term "phosphonate" is a typographical error and should instead read "phosphate", as evidenced by the recitation of "phosphate" on page 2, line 28; page 3, line 10; and in the practical example of page 8, line 15 of the specification.

Art Unit: 1764

Regarding claim 18, Levy et al. further disclose the adsorbent material may comprise activated charcoal (i.e. derived from wood charcoal; column 7, lines 44-53).

Instant claims 14, 16-18 read on the composition of Levy et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 1-13 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levy et al. (U.S. 4,081,402) in view of Lennon et al. (U.S. 4,999,163).

Regarding claims 1 and 21, Levy et al. disclose an absorbent matrix (i.e. hydrophilic polymer or hydrogel matrix; column 4, line 37-column 6, line 46) comprising a humectant (i.e. ethylene glycol, glycerol; column 4, lines 59-65), a pH-stabilizing agent (i.e. phosphate buffer of pH 7.6; column 13, lines 38-40; column 14, lines 18-24) and an absorbent material (i.e. activated carbon, ion exchange resins; column 7, lines 31-55). Levy et al. further disclose the absorbent matrix is insertable into at least one receptacle having an open end (i.e. group of test tubes; FIG. 2; column 11, lines 35-50; column 13, lines 34-53). Although Levy et al. are silent as to whether the receptacle may comprise a lid and a means for affixing the lid securely to the receptacle, it

would have been obvious for one of ordinary skill in the art at the time the invention was made to provide a lid and means for affixing the lid to the receptacle of Levy et al., because the use lids for sealing the contents of a receptacle, such as an absorbent, is conventionally known in the art, as evidenced by Lennon et al. (i.e. receptacle **12** comprising a lid element **30**, with means for affixing the lid securely to the receptacle; Abstract; FIG. 2). Furthermore, the Examiner takes Official Notice that it is obvious to provide lids and a means for affixing lids to receptacles, in order to seal the contents within a receptacle.

Regarding claim 2, no further structural limitations are recited and therefore the modified apparatus of Levy et al. meets the claim. In any event, Levy et al. further disclose the apparatus may be used for the radioimmunoassay of antigens with ^{125}I , for example (column 13, line 3 to column 14, line 44).

Regarding claim 3, no further structural limitations are recited and therefore the modified apparatus of Levy et al. meets the claim. In any event, Levy et al. further disclose the apparatus may be used for the radioimmunoassay of antigens with ^3H , for example (column 14, line 46 to column 15, line 12).

Regarding claims 4-5, Levy et al. further disclose the absorbent matrix may be deposited within a cylinder or article constructed of glass or inert plastic (column 2, lines 60-65).

Therefore, it would have been an obvious design choice for one of ordinary skill in the art at the time the invention was made to provide a glass or plastic receptacle, depending on the intended use of the apparatus and absent showing unexpected results. Furthermore, selection of glass or plastic for construction of an absorbent receptacle is conventionally known in the art, as evidenced by Lennon et al. (column 6, lines 38-44).

Regarding claim 6, Levy et al. further disclose said absorbent matrix is constructed of one or more synthetic materials (column 5, line 19 to column 6, line 46).

Regarding claim 7, Levy et al. are silent as to whether the absorbent matrix may comprise a natural material. However, it would have been obvious design choice for one of ordinary skill in the art at the time the invention was made to select a natural material for the absorbent matrix in the modified apparatus of Levy et al. because the use of natural materials as absorbent matrices is conventionally known in the art, as evidenced by Lennon et al. In particular, Lennon et al. cite the conventionality of selecting cotton fiber, paper and other cellulosic material (column 6, lines 49-57).

Regarding claim 8, Levy et al. further disclose said synthetic material may comprise polyacrylamide (column 5, lines 34-44) and hydrophilic polymers (column 5, line 19+). Levy et al. further cite prior art use of dextrans (column 2, lines 3-14).

Regarding claim 9, Levy et al. are silent as to whether the absorbent matrix may comprise unidirectional cotton fibers. Lennon et al. teach a device (column 4, line 53 to column 5, line 2) having an absorbent plug of conventionally known materials such as cotton fibers and having capillary passages extending therethrough which are both transverse to and generally parallel to the surfaces at the upper and lower ends of the plug. The plug inherently comprises unidirectional fibers, as in the stated examples of a cigarette filter or tampon (column 6, line 45 to column 7, line 2). It would have been obvious for one of ordinary skill in the art at the time the invention was made to select unidirectional cotton fibers for the absorbent matrix in the modified apparatus of Lennon et al. because such cotton fibers are capable of absorbing aqueous materials while possessing sufficient structural integrity, as taught by Lennon et al.

Regarding claims 10-11, Levy et al. further disclose the pH-stabilizing agent may comprise a dibasic phosphate salt (i.e. dibasic potassium phosphate; column 14, lines 18-24). Although the claim recites specifically "dibasic phosphonate salts", it is interpreted by the Examiner that the use of the term "phosphonate" is a typographical error and should instead read "phosphate", as evidenced by the recitation of "phosphate" on page 2, line 28; page 3, line 10; and in the practical example of page 8, line 15 of the specification. Further evidence is the use of the terms "tribasic phosphonate salts", which does not exist since a phosphonate salt may be at most dibasic, and therefore "phosphonate" is again interpreted as meaning "phosphate".

Regarding claim 12, Levy et al. further disclose said adsorbent material may comprise polymeric resins (column 7, line 54- column 9, line 23).

Regarding claim 13, Levy et al. further disclose said adsorbent material may comprise activated charcoal (i.e. activated carbon derived from wood charcoal; column 7, lines 44-53).

9. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Levy et al. (U.S. 4,081,402), as applied to claim 14 above, and further in view of Lennon et al (U.S. 4,999,163). Levy et al. are silent as to whether the absorbent matrix may be constructed of unidirectional cotton fibers. The same comments with respect to Lennon et al. apply (see claim 9 above).

10. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Levy et al. (U.S. 4,081,402) in view of Dean (*Lange's Handbook of Chemistry*).

Levy et al. disclose the absorbent matrix may comprise glycerol (column 4, lines 61-65), dibasic potassium phosphate (column 14, lines 18-24) and activated charcoal (column 7, lines 44-53). Although Levy et al. are silent as to the specifically disodium phosphate salts, it would

Art Unit: 1764

have been an obvious design choice for one of ordinary skill in the art at the time the invention was made to substitute disodium phosphate salts for dibasic potassium phosphate in the composition of Levy et al., since both compounds are capable of stabilizing pH and are known equivalents for achieving a specific pH. As illustrated by Dean, use of disodium phosphate salt, as well as dibasic potassium phosphate, is well known in the art (Table 8.14, columns 6 and 7). In any event, the substitution of known equivalents involves only ordinary skill in the art. *In re Fout* 213 USPQ 532 (CCPA 1982); *In re Susi* 169 USPQ 423 (CCPA 1971); *In re Siebentritt* 152 USPQ 618 (CCPA 1967); *In re Ruff* 118 USPQ 343 (CCPA 1958).

Levy et al. are silent as to specifically about 3-20 parts glycerol, 1-10 parts dibasic potassium phosphate (equivalent to disodium phosphate) and 0.5 - 10 parts activated charcoal. However, Levy et al. disclose the amount of glycerol added will depend on the level of hydration desired (i.e. partially or fully hydrated; column 4, lines 59-65) and therefore it would have been an obvious design choice for one of ordinary skill in the art at the time the invention was made to modify the parts of glycerol to be about 3-20 parts, depending on the intended use and absent showing unexpected results. Levy et al. further disclose the parts of pH stabilizer will depend on the desired pH level (i.e. a pH of 7.6 in Example 2; column 13, line 3 to column 14, line 44), and therefore it would have been an obvious design choice for one of ordinary skill in the art at the time the invention was made to modify the parts of pH stabilizer to be about 1-10 parts to achieve a specific pH level, depending on the intended use of the composition and absent showing unexpected results. Finally, Levy et al. disclose that the amount of activated charcoal in the composition will depend on the dimensions of the matrix (i.e. FASTAB, added in step 4; column 13, lines 34-53). In Example 1, for instance, Levy et al. disclose the use of 20 grams of

Art Unit: 1764

activated charcoal for forming disks of approximately 8 mm diameter and 4 mm thickness (column 12, lines 11-42), which are later inserted into test tubes. Therefore, it would have been an obvious design choice for one of ordinary skill in the art at the time the invention was made to modify the parts of activated charcoal to be about 0.5-10 parts by simply modifying the dimensions of the punched disks, depending on the intended use of the composition and absent showing unexpected results, since it has been held that changes in size involve only ordinary skill in the art. *In re Rose*, 220 F.2d 459, 463, 105 USPQ 237, 240 (CCPA 1955).

Please note that although the claim recites specifically "disodium phosphonate salts", it is interpreted by the Examiner that the use of the term "phosphonate" is a typographical error and should instead read "phosphate", as evidenced by the recitation of "phosphate" on page 2, lines 30-31; page 3, line 10; and in the practical example of page 8, line 15 of the specification.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: McDonnell et al. and Bulat are presented to illustrate the state of the art.

* * *

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer A. Leung whose telephone number is 703-305-4951. The examiner can normally be reached on 8:30 am - 5:30 pm M-F, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Glenn A. Caldarola can be reached on 703-308-6824. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Jennifer A. Leung *JAL*
January 21, 2003

Hien Tran
HIEN TRAN
PRIMARY EXAMINER